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10/533,926	05/04/2005	Hans-Rainer Hoffmann	512100-2046	8229

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EXAMINER

ORWIG, KEVIN S

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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MAR 16 2009

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In re Application of:
 Hoffmann et al.
 Serial No.: 10/533,926
 Filed: October 17, 2003
 Attorney Docket No.: 512100-2046

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 : PETITION DECISION
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This is in response to the petition under 37 CFR § 1.181, filed on February 10, 2009, which requests withdrawal of finality instituted in the Office action mailed January 23, 2009.

BACKGROUND

The examiner mailed a non-final Office action on May 28, 2008 setting a three month shortened statutory period for reply. In this Office action, claims 1-11 were pending. Claims 5-10 were rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement; claim 6 was rejected under 35 USC 112, first paragraph, and as failing to comply with the enablement requirement and claims 1-11 were rejected under 35 USC 112, second paragraph as being indefinite. Claims 1-5 were rejected under 35 USC 103 (a) as unpatentable over Zhang et al. in view of Patel et al. and in further view of Weete et al., as evidenced by Stedman's Medical Dictionary, and by Raisch et al. Claims 1, 6, and 7 were rejected under 35 USC 103 (a) as unpatentable over Zhang et al. in view of Patel et al. and in further view of Shen et al. Claims 1 and 8 were rejected under 35 USC 103 (a) as unpatentable over Zhang et al. in view of Meyer et al. Claims 1 and 9 were rejected under 35 USC 103 (a) as unpatentable over Zhang et al. in view of Patel et al. and in further view of Cary. Claims 1 and 10 were rejected under 35 USC 103 (a) as unpatentable over Zhang et al. in view of Patel et al. and in further view of Plotnikoff et al. Claims 1 and 11 were rejected under 35 USC 103 (a) as unpatentable over Zhang et al. in view of Patel et al. and in further view of Serra et al.

On October 28, 2008, applicants filed arguments traversing the examiner's rejections instituted in the non-final Office action of May 28, 2008. In this response, applicants amended claims 1, 7, 9 and 10; and cancelled claims 2, 5, 6 and 8. Applicants also added new claims 12 and 13.

The examiner mailed a final Office action on January 23, 2009 setting a three month shortened statutory period for reply. In this Office action, claims 1, 3, 4, 7, and 9-13 were pending. Claims 1, 3, 4, 7, and 9-13 were rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement and rejected under 35 USC 112, second paragraph as being indefinite. Claims 1, 3, 4, and 12 were rejected under 35 USC 103 (a) as unpatentable over Zhang et al. in view of Patel et al. and in further view of Weete et al., as evidenced by Stedman's Medical Dictionary, and by Raisch et al. Claims 1 and 7 were rejected under 35 USC 103 (a) as unpatentable over Zhang et al. in view of Patel et al. and Weete et al. and in further view of Shen et al. Claims 1 and 9 were rejected under 35 USC 103 (a) as unpatentable over Zhang et al. in view of Patel et al. and Weete et al., and in further view of Cary. Claims 1 and 10 were rejected under 35 USC 103 (a) as unpatentable over Zhang et al. in view of Patel et al. and Weete et al. and in further view of Plotnikoff et al. Claims 1 and 11 were rejected under 35 USC 103 (a) as unpatentable over Zhang et al. in view of Patel et al. and Weete et al., and in further view of Serra et al. Claim 13 was rejected under 35 USC 103 (a) as unpatentable over Zhang et al. in view of Patel et al. and Weete et al., as applied to claims 1, 3, 4 and 12 above, and in further view of Majete.

In response thereto, applicants filed this petition under 37 CFR § 1.181 on February 10, 2009 requesting withdrawal of finality of the Office action mailed January 23, 2009.

DISCUSSION

The petition and the file history have been carefully considered.

In this petition filed on February 10, 2009, applicants request withdrawal of the final rejection of January 23, 2009 as new ground of rejections were made by the examiner which were not necessitated by the applicants' amendments. Specifically, applicants argue "The final rejection mailed on 23 January 2009 withdrew all previous rejections made in the Office Action of 28 July 2008 and introduced a new 35 U.S.C. 112, **first paragraph rejection based on new matter, a new 35 U.S.C. 112, second paragraph rejection and new 35 U.S.C. 103** rejections of claim 13 over Zhang in view of Patel, Weete and Majeti. Further, applicants argue that their "amendment did not necessitate the new grounds of rejection under 35 U.S.C. 103 because the result of the applicants' claim amendments served to narrow the scope of the claims under consideration and did not introduce new limitations which were not previously disclosed in the claims, i.e. the scope of the claims under examination were disclosed in the originally filed claims".

Applicants also argue the guidelines for conducting a search are recited in MPEP 904.03 which states in part:

"It is a prerequisite to a speedy and just determination of the issues involved in the examination of an application that a careful and comprehensive search, commensurate with the limitations appearing in the most detailed claims in the case, be made in preparing the first action on the merits so that the second action on the merits can be made final or the application allowed with no further searching other than to update the

original search. It is normally not enough that references be selected to meet only the terms of the claims alone, especially if only broad claims are presented; *but the search should, insofar as possible, also cover all subject matter which the examiner reasonably anticipates might be incorporated into applicant's amendment.* Applicants can facilitate a complete search by including, at the time of filing, claims varying from the broadest to which they believe they are entitled to the most detailed that they would be willing to accept.

In doing a complete search, the examiner should find and cite references that, while not needed for treating the claims, would be useful for forestalling the presentation of claims to other subject matter regarded by applicant as his or her invention, by showing that this other subject matter is old or obvious." (emphasis added)

However, it is pointed out that MPEP §706.07(a) states: "A second or any subsequent action on the merits in any application or patent involved in reexamination proceedings should not be made final if it includes a rejection, on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed. However, an examiner cannot be expected to foresee whether or how an applicant will amend a claim to overcome a rejection except in very limited circumstances (e.g., where the examiner suggests how applicant can overcome a rejection under 35 U.S.C. 112, second paragraph)." In the present instance, the examiner could not reasonably foresee how applicants would amend these claims. Specifically, the original claims were narrowed, thereby, overcoming the rejections of record and required the examiner to set forth a new ground of rejection. Therefore, applicants' arguments pertaining to the new rejections of the claims are not persuasive.

Applicants also argue "With regard to the rejections based on use of the phrase ---salts thereof---, clearly salt forms are a type of derivative and which is well known to those of ordinary skill in the pharmaceutical art and should have been anticipated as being a part of an amendment to the claim. (There is no basis for the rejection based on lack of written description as salt forms of pharmaceutical compounds have been well established in the art. Moreover, there was no basis for lacking adequate metes and bounds as one of ordinary skill in the art would be able to determine whether an active agent was a salt form or not.) In addition, the amendment to recite salt forms was not presented as a concession that the original rejection was proper, but a good faith effort to advance prosecution of the application." Applicants' argument has been considered but it is not persuasive. Whether or not the rejections per se are proper will not be dealt with herein as this is an appealable matter not a petitionable one. What will be considered is whether the examiner, in making the rejections, properly made the Office action final. It is decided that the Office action was properly made final as the limitation "salts thereof" was not present in the original claims and was added in the amended claims of October 28, 2008. An examiner also cannot be expected to foresee whether or how an applicant will amend a claim to overcome a rejection except in very limited circumstances. Specifically, finality of Office actions on a second action is governed by MPEP § 706.07(a):

Under present practice, second or any subsequent actions on the merits shall be final, *except where the examiner introduces a new ground of rejection that is neither*

necessitated by applicant's amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). Where information is submitted in an information disclosure statement during the period set forth in 37 CFR 1.97(c) with a fee, the examiner may use the information submitted, e.g., a printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. (emphasis added)

Therefore, the MPEP establishes that new rejections may be made in final Office actions so long as the new rejections are necessitated by applicants' amendment(s) to the claims, or based upon information submitted in an information disclosure statement. It is evident that upon amending the claims to recite "salts thereof", the examiner was of the opinion that new rejections were necessary and making the Office action final was proper.

Finally, applicants agree "the rejection of claim 13 introduces a new reference previously not relied upon by the Examiner, i.e. the Majeti reference. As noted above, the elements of Claim 13 were already present in original claim 1 and therefore should have been examined in the first Office Action on the merits and/or anticipated as a possible claim amendment." This argument is also not persuasive since claim 13, which is new, is a combination of original claim 1 and 2. More specifically, claim 1 states (a) or (b). New claim 13 is a combination of (a) and (b) and claim 2. Therefore, newly added claim 13 sets forth a different limitation with a different scope, thus requiring the newly added reference of Majeti.

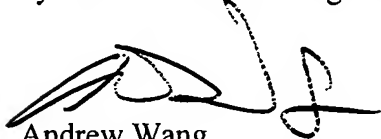
Thus, applicants' arguments are not persuasive that the final Office action of January 23, 2009 was improper and the finality of said Office action will not be withdrawn.

DECISION

The petition is **DENIED**.

Any new or renewed petition must be filed within TWO MONTHS of the mail date of this decision.

Should there be any questions about this decision please contact Marianne C. Seidel, by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0584 or by facsimile sent to the general Office facsimile number, 703-872-9306.



Andrew Wang
Acting Director, Technology Center 1600